

## **REMARKS**

Claim 18 has been amended. As amended, the last clause of claim 18 starting with “a processor” differs from originally filed claim 18 only in that the phrase “i.) to initiate analysis algorithms prior to completion of temperature cycling, ii.) to use the algorithms” has been added. Thus, support for claim 18 in the present listing of claims is found in originally filed claim 18. Support for amended claim 18 is also found on page 2, lines 13-15 of the specification and on page 13, lines 22-25 of the specification.

Applicants wish to thank Examiner Smith for the courtesies extended by the Examiner in the telephonic interview with Applicants’ undersigned attorney on November 1, 2005. Proposed amendments to claim 18 were discussed. An agreement was not reached with respect to allowance of the claims, but the Examiner was favorable towards the present amendment to claim 18. However, the Examiner wishes to review the file history to confirm that the present amendment resolves all previous issues raised by the Examiner in this application and overcomes the rejection of the claims over Schork et al.

The Examiner has rejected claims 18-23 under 35 U.S.C. § 112, ¶ 2 for indefiniteness. In the first paragraph of the rejection on page 2 of the office action, the Examiner objects to the phrase “a processor means” in claim 18 as amended in the previous response, filed on April 22, 2005. Applicants have deleted the phrase “a processor means” from claim 18.

In the second paragraph of the rejection on page 3 of the office action, the Examiner indicates that the phrase “a processor means” is not interconnected to the method steps that follow. The Examiner also states that “[i]n the previous set of claims, Applicants recited “the processor is programmed to obtain” which clearly limited the processor to one programmed to perform the method steps.” See page 3, lines 5-7 of the office action. Applicants have amended claim 18 so that the language with regards to the programming of

the processor is the same as the language in claim 18 of Applicants' response, filed on January 24, 2005. The January 24, 2005 response is the response referred to by the Examiner in the preceding passage from the Examiner's office action. Thus, Applicants have amended claim 18 to correspond to the previous set of claims for which the Examiner believes the phrase "the processor" is clearly programmed to perform the method steps.

In the third paragraph of the rejection on page 3 of the office action, the Examiner indicates that there is no antecedent basis for "the processor" in line 9 of claim 18. Applicants have amended claim 18 to provide antecedent basis for "the processor" in claim 18. Withdrawal of the rejection of claims 18-23 under 35 U.S.C. § 112, ¶ 2 is respectfully requested.

The Examiner has also rejected claims 18-23 under 35 U.S.C. § 102(a) and 102(e) as being anticipated by Schork et al. (U.S. Patent No. 6,291,182; hereinafter the '182 patent). Applicants respectfully traverse the Examiner's rejection. The '182 patent does not anticipate claim 18, as amended, or its dependent claims 19-23.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Claim 18 of the above-captioned application specifies a processor "programmed to initiate analysis algorithms prior to completion of temperature cycling" to clarify that a characteristic of the claimed device is that the processor is programmed to initiate analysis algorithms prior to completion of temperature cycling. As stated by the Examiner on page 3 of the present office action a processor programmed to perform certain method steps "clearly limits the processor to one programmed to perform the method steps." The '182 patent does not describe a processor programmed to initiate analysis algorithms prior to completion of temperature cycling to ascertain whether a nucleic acid is present in a sample.

The Examiner indicates that the '182 patent discloses a fluorimeter and Picogreen to determine quantities of amplification products and refers to column 47, lines 7-9 of the '182 patent (Example 6). However, although Example 6 discloses a fluorimeter and the use of Picogreen to quantitate nucleic acids, the fluorimeter and Picogreen are used to determine quantities of amplification products after temperature cycling is complete in samples from the amplification reaction after final elongation that are aliquoted into 96-well plates. Thus, the quantities of amplification products are determined after the temperature cycling is complete (see column 47, lines 1-9).

The Examiner also refers to the sequencing method described in Example 6 and indicates that the '182 patent discloses the use of dideoxy terminator sequencing reactions to determine sequences of amplification products wherein the sequence data is evaluated using software designed to detect sites among the amplified products via different fluorescent molecules and by evaluating intensity ratios. The Examiner refers to column 47, lines 10-15 and column 47, lines 10-28 in Example 6 of the '182 patent. However, the sequencing reactions described in Example 6 of the '182 patent are done using dideoxy terminators, each labeled with a different fluorescent molecule, and the sequences are analyzed by running the products of the sequencing reaction on sequencing gels and then using gel image analysis of the sequencing gels to determine the sequences (see column 47, lines 11-36). The sequence data from the gel image analysis is evaluated using software designed to detect the presence of a nucleic acid in a sample. Thus, the analysis described in Example 6 is not done before temperature cycling is complete. Rather the gel image analysis is done on samples run on a sequencing gel and the samples are run on the sequencing gel long after temperature cycling is complete. A similar method is described in Example 17 and is also referred to by the Examiner.

The Examiner comments on the phrase “during amplification” as including steps involving amplified products after amplification is complete. However, this phrase is no longer included in claim 18.

The ‘182 patent describes only data collection for samples that have been aliquoted into a microtiter plate and are no longer undergoing the polymerase chain reaction (as described in Example 6 of the ‘182 patent) or samples that are being run on a sequencing gel and are no longer undergoing the polymerase chain reaction (as described in Examples 6 and 17 of the ‘182 patent). Accordingly, for the devices and methods described in the ‘182 patent, the analysis is done long after temperature cycling is complete. No where does the ‘182 patent describe a processor “programmed to initiate analysis algorithms prior to completion of temperature cycling.” Thus, the ‘182 patent does not describe all of the required elements of claims 18-23 and the ‘182 patent cannot anticipate claims 18-23. Withdrawal of the rejection of claims 18-23 under 35 U.S.C. § 102(a) and 102(e) is respectfully requested.

### **CONCLUSION**

The foregoing amendments and remarks are believed to fully respond to the Examiner’s rejection. The amended claims are in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance.

Respectfully submitted,



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